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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,593	03/30/2004	Bernard Andreas	021629-002500US	5895

20350 7590 09/08/2009
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EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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09/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/814,593	Applicant(s) ANDREAS ET AL.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02172009, 12152008, 11132008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/03/08 has been entered.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In this case, the disclosure of the prior-filed application, Application No. 10/637,713, fails to provide adequate support or enablement in the manner provided by

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the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior filed application provides support for a multiple stent delivery device as in Figs. 1-2b and 7a-8. The prior filed application further provides support for stent segments (placed in a main branch) having side wall openings that can be expanded by a balloon dilation catheter where a catheter can be used to place stents in the side branch. However there is no support for using the multiple stent delivery device in a method of delivering a first stent to a main branch and delivering a second stent to a side branch. The only mention of delivering stents to a side branch is paragraphs [0100] and [0104] in the '713 application, which is where applicant points to for support of the claimed invention. However, close inspection of these paragraphs (or anywhere else in the specification) does not indicate that the delivery catheter that is used to place the first stent in the main branch is the same delivery catheter that is used to place the second stent in the side branch as required by claims 53 and 64. For example Paragraph [0100] states "*a balloon dilatation catheter may be positioned through a circumferential slot 104 and expanded,*" and "*a catheter may be inserted through stent segment 32 and into the side branch for placing stents*".

Therefore the effective filing date for the purposes of applying art will be the filing date of the instant application, 03/30/2004.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63, 65, 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The aforementioned claims recite, "An expandable member". It is unclear whether this limitation is meant to: a) refer back to "an expandable member" recited in claims 53 and 64, in which case applicant is requested to use "the expandable member" in the claims; or b) indicate a new element into the device in which case applicant is reminded of that these claims would be directed to an invention that is independent or distinct from the invention originally claimed and therefore should be withdrawn as being directed to a non-elected species.

For the purpose of examination, examiner will treat the limitation as having antecedent basis to claims 53 and 64.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 53-62, 64, 67-71 and 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0793873) in view of Poncet (US 5,833,694) and further in view of Brucker (US 2002/0793873).

6. Chermoni discloses a method of treating one or more lesions in a vessel, the vessel, the method comprising: positioning a delivery catheter (Fig. 11) in the main

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branch, the delivery catheter having an expandable member (704) disposed thereon and first (206a) and second stents (206b) unconnected with one another and positionable over the expandable member (Fig. 12); radially expanding the expandable member thereby radially expanding the first stent in the main branch; positioning the delivery catheter at a different location; and radially expanding the expandable member thereby radially expanding the second stent in the side branch; wherein the delivery catheter remains in the vessel between radially expanding the first and second stents (Para [009]). Chermoni further discloses deploying a third stent (206c); the first and second stents each comprise a plurality of separable segments (where the segments are struts which are separable upon expansion of the stent); the first stent has a different length than the second stent (Para [0005]; [0047]); the first stent can be deployed before the second stent or the second stent can be deployed before the first stent (Para [0049]); adjusting the length of the first and second stent before deploying the first stent while the delivery catheter remains in the vessel (Para [0008] states that the stents may be delivered in any order and may be different lengths and so the lengths are adjusted by choosing a different order of stents); selecting a first number of separable segments for radial expansion and selecting a second number of separable segments for radial expansion different from the first (where all the separable segments would be chosen and would be different since stents are different sizes); the step of selecting comprises moving a sheath or a pusher tube (where 114 can be a sheath or a pusher tube).

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7. Chermoni does not disclose that the stents positionable (capable of being positioned) over the expandable member in direct engagement with one another when unexpanded. However Poncet discloses a multiple stent delivery device where the stents are in direct engagement with each other when unexpanded (Fig. 1a). Poncet also discloses a similar embodiment with spacers between the stents similar to that of Chermoni. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Chermoni such that the stents engage one another when unexpanded. Poncet shows that the two structures were art recognized equivalents at the time of the invention was made, and so, one of ordinary skill in the art would have found it obvious to substitute one for the other, since substitution of one known element for another would have yielded predictable results, namely an efficient way of delivering multiple stents.

8. Chermoni modified by Poncet does not disclose a method that incorporates delivering a second stent to a side branch or that the delivery catheter is positioned through an opening in a sidewall of the first stent to deploy the second stent.

9. However, Brucker discloses a method of treating one or more lesions in a vessel, the vessel having a main branch and a side branch branching from the main branch at a bifurcation, the method comprising similar steps to those that are disclosed by modified Chermoni such as positioning the delivery catheter at multiple lesions and expanding first and second stents at different locations without removing the catheter from the body. Brucker further discloses positioning a delivery catheter (112) in the main branch, and radially expanding the expandable member thereby radially expanding a first stent

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(94 or 114) in the main branch across the bifurcation (Fig. 13, 14, 17 and 18; Para [0083]); positioning the delivery catheter in the side branch and radially expanding an expandable member (120) thereby radially expanding a second stent (74 or 116) in the side branch (Fig. 10-12, 20, Para [0084]); wherein the delivery catheter is not removed from the vessel between deploying the first and second stents (see Figs. 18-20; Para [0084]); the delivery catheter is positioned through an opening (16) in a sidewall of the first stent to deploy the second stent (Fig. 20); wherein the first stent and the second stent each have a portion in the main branch. (Fig. 14, 16, 17); wherein the first stent has a first portion with a plurality of first slots (for example at scaffold 14) and a second portion with a plurality of second slots (openings formed by mesh pattern in rest of stent), the first slots being larger than the second slots; wherein the opening in the sidewall of the first stent comprises one of the first slots, and wherein the first stent is deployed so that at least one of the first slots is aligned with bifurcation (for example Figs. 7 and 15); wherein the first stent has a different geometry than the second stent (the first stent has a side opening).

10. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the method of treating a bifurcated vessel into the method and apparatus of modified Chermoni. Both modified Chermoni and Brucker disclose similar devices for multiple stent delivery. Brucker discloses an additional method of delivering the multiple stents to lesions in a bifurcated vessel having a main vessel and a branch vessel. One of ordinary skill would have been capable of applying this known technique of enhancement (delivering stents to a bifurcated vessel) to a base device

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(multiple stent delivery catheter) in order to yield predictable results namely providing an efficient way of delivering multiple stents to multiple lesions at a bifurcation. If a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, applying the technique to a similar device would have been obvious.

1. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US 2002/0156496) in view of Brucker et al. (US 2002/0193873) as applied to claim 12 above and further in view of Loos et al (US 6,579,309).
2. Chermoni modified by Brucker discloses a method of treating a lesion in a bifurcation but does not disclose that the stent delivered to the main branch has an opening that is I-shaped. However, Loos discloses a stent that is intended to be delivered to a main branch of a bifurcation. The stent has side openings that are I-shaped (Fig. 3, for example where Arrows 19 and 20 are pointing). The stent has a plurality of first slots (I shaped openings) larger than a plurality of second slots (for example where 13 and 18) are pointing. The first slots are intended to be aligned with the bifurcation. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the stent of Loos into the delivery device and method of Chermoni modified by Brucker. Chermoni modified by Brucker discloses the claimed method except for a stent with a flower shaped opening rather than an I-shaped opening. Loos shows that a stent with an I-shaped opening is an equivalent structure known in the art. Therefore, because the two stents were art recognized equivalents at

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the time of the invention was made, one of ordinary skill in the art would have found it obvious to substitute the I-shaped opening for the flower shaped opening, since substitution of one known element for another would have yielded predictable results.

11. Claims 63, 65 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni in view of Brucker as applied to claims 1 and 12 above and further in view of Shaknovich (US 5,807,398).

12. Chermoni modified by Brucker does not explicitly state the step of dilating at least one lesion in the vessel using an expandable member on the delivery catheter before deploying at least one of the first and second stents. However, Chermoni does contemplate the multiple steps of balloon angioplasty and stent delivery when discussing prior art (Para [003]).

13. Shaknovich discloses a single catheter multiple stent delivery device similar to Chermoni modified by Brucker and explicitly discloses using the expandable member to pre-dilate a vessel prior to stent delivery in order to provide an adequate passageway for the delivery catheter (C 12: 20-29). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the step of dilating a lesion prior to stent delivery into the method disclosed by Chermoni modified by Brucker. Pre-dilating the vessel prior to stent delivery is old and well known in the art and provides the advantage of increasing the diameter of the passage to allow the catheter to get through.

Response to Arguments

14. Applicant's arguments regarding priority, filed 10/07/08, have been fully considered but they are not persuasive.

15. Regarding the issue of priority examiner does not find applicant's argument persuasive. Applicant admits that the '713 application does not "expressly state that both the main vessel lesion and the bifurcation lesion are stented using the same catheter". Applicant goes on to provide the rationale that, "one of ordinary skill in the art would appreciate that the catheter could be used to treat both branches without removing the catheter from the patient," (Remarks, p.9). Examiner is not convinced that this rationale is sufficient to provide support for the earlier filing date. The disclosure of the '713 application is broader than the invention that is claimed in the instant application and therefore it does not anticipate the claims of the current application. The '713 application provides two separate pieces of information and requires one of skill to combine these teachings using obviousness rationale (as stated by applicant in remarks and repeated above). Examiner asserts that if one needs to rely on obviousness rationale to show support for the claimed invention, then it should be clear that the '713 application does not provide adequate support for the claimed invention of the instant application.

16. Applicant's arguments with respect to claim 53-78 with respect to prior art have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/13/09